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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/728,327	JORGENSEN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Karlheinz R. Skowronek whose telephone number is (571) 272-9047.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2007 has been entered.

Claim Status

Claims 37-61 are pending.

Claims 1-36 are cancelled.

Claims 56-61 are new.

Claims 37-61 are being examined.

Claim Rejections - 35 USC § 112

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 -61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37 and 53 are unclear with respect to the recitations of “a fluid distribution module”. Claims 37 and 53 both recite a supply module having a fluid distribution module at line 2 of both claims 37 and 53 and a fluid distribution module at line 7 of both claims 37 and 53. A lack of clarity rises in both claims due to the multiple recitations of "a fluid distribution module". The multiple recitations of "a fluid distribution module" are unclear because one can not ascertain from the claim if “a fluid distribution module” of line 2 is the same or different from the module of line 7. Claims 38-52 and 56-58 are also rejected because they depend from claim 37, and thus contain the above issues due to said dependence. Claims 54-55 and 59-61 are also rejected because they depend from claim 53, and thus contain the above issues due to said dependence.

Claims 49 and 50 refer to an “air module”. The specification does not provide a definition for "air module". The specification does show that the supply module comprises a compressor, air reservoir and filter. It is unclear if the claimed air module is analogous to the compressor, air reservoir and filter described in the specification. The examiner suggests amendment of the claim 49 to recite “wherein the supply module further comprises a compressor, air reservoir and filter" and amendment of claim 50 to recite “where the filter is a 0.2 micron filter”.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments, see remarks, filed 31 October 2007, with respect to the rejection(s) of claim(s) 37-41, 44-49 and 51-44 under 35 USC 103(a) as unpatentable over Hei et al. in view of Kobashi et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn in view of amendments to the claims. However, upon further consideration, a new ground(s) of rejection is made in view of Hei et al. in view of Kobashi et al. and in view of DeVries.

Applicant's arguments, see remarks, filed 31 October 2007, with respect to the rejection of claims 42-43 and 50 under 35 USC 103(a) as unpatentable over Hei et al. in view of Kobashi et a and in further view of Matkovich et al. have been fully considered and are persuasive. The rejection of claims 42-43 and 50 has been withdrawn in view of amendments to the claims.

Applicant's arguments, see remarks, filed 31 October 2007, with respect to the rejection of claim 55 under 35 USC 103(a) as unpatentable over Hei et al. in view of Kobashi et a and in further view of Hudak have been fully considered and are persuasive. The rejection of claim 55 has been withdrawn in view of amendments to the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37-41, 44-49, 51-54, and 56-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei.et al. (US PAT 6,544,727) in view of Kobashi (U.S. PAT 5,428,993) and in view of DeVries (US PAT 4, 379, 452).

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution

module and a plurality of sensors. In some embodiments, the sensors include pressure, optical, mass flow, temperature, volume determination or volume detection devices. In some embodiments, supply containers store process chemicals. In some embodiments, process chemicals are selected from the group of citric acid, sodium phosphate, sodium chloride, water, polyethylene glycol, saline, isotonic buffers, glycan modifying enzymes, and glycan modifying enzyme buffers . In some embodiments, the processing module comprises a centrifuge system. In some embodiments, the processing module includes a heat transfer system. In some embodiments, the processing module includes a processing chamber. In some embodiments, the processing module includes a variable-volume processing chamber. In some embodiments, the processing module includes an expressor system. In some embodiments, the processing module includes an air module. In some embodiments, the air module includes a 0.2-micron filter. In some embodiments, the system comprises a waste module. In some embodiments, the fluid distribution module comprises a plurality of pumps adapted to the control module and the supply container. In some embodiments, the fluid distribution module comprises a pump for transferring fluid through the fluid distribution module.

Hei discloses a system for the decontamination biological fluids (e.g., blood) (abstract and col. 66-68). Hei discloses a supply module (fig. 51, elements 508, 539, and 560). Hei discloses a cell module (fig. 5 I, elements 500, 528, and 538). Hei discloses a processing module (e.g., element 538 of fig. 51; a block disclosed on fig. 1 and 3; an element where blood and a chemical is mixed on fig. 206-C). Hei discloses a control module (fig; 5 1, element 550). Hei discloses a plurality of conduits connecting

the supply module to the processing module, and the cell module to the processing module (fig. 49-5 1 and 20A-C). Hei discloses a plurality of valves adapted to the control module and other modules (ports, see fig. 49-51,20A-C, and 37). Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids (col. 65, line 30-47). Hei disclose controlling temperature (col. 71, line 63-65; col. 72, line 55-64), flow (col. 66, line 40-65) and volume (col. 68, line 14-40) and an optical device (col. 100, line 28-38). Hei discloses supply containers containing process chemicals (fig. 20, 37, and 49-51; col. 68, line 14-67). Hei discloses phosphate salts, HEPES, citrates, physiological buffers, and anticoagulants (col. 69-70, col. 66, line 40-44). Hei discloses sterile docking, sterile filters, resin (chemical), sterile bags, sterile tubes, sterile tubing, and housing (col. 97, line 29-38 and claim 28). Hei discloses an inline filter (claims 1 and 21). Hei discloses a centrifuge system (fig. 49-51, element 520).

Hei discloses a heat transfer system (col. 72, line 53-67). Hei discloses processing chamber (element 538, fig. 51 and fig. I). Hei discloses variable volume processing chamber (fig. 20 and 37; col. 97, line 40-65). Hei discloses an expression system (col. 97, line 40-67). Hei discloses an air module (col. 73, line 1-3). Hei discloses a waste module (a mesh pouch) (col. 121, line 45-61). Hei discloses pumps (elements 51, 6, 506, 536, 526, and 556 of fig. 51). Hei discloses the blood cells as being erythrocytes (col. 12, line 18).

Although Hei discloses sensors for calculating weight and volume of reinfused fluids and defining quantity of blood cells (col. 68, line 14-24; col. col. 65, line 30-47),

Hei does not specifically disclose a weight sensor or confirming the correct delivery of a chemical by measuring a change in weight. Hei et al. does not show a fluid distribution module comprising a plurality of ports.

Kobashi discloses a weight sensor for chemical reagents to be used in automatic analyzers that confirms correct delivery of a chemical by measuring change in weight (for example, column 2, lines 1-25).

DeVries shows a fluid distribution module for processing cells. DeVries shows the fluid distribution module comprises a plurality of conduits, a plurality of ports and a plurality valves (figure 4). DeVries shows the system is closed to environmental contaminants and providing for sterile processing (col. 2, lines 30-32). DeVries shows the fluid distribution module comprises a pump (col. 5, line 50-53). DeVries shows the plurality of conduits comprises a single use disposable device (col. 3, line 50). DeVries shows an advantage of closed fluid distribution module is that it simplifies the handling of complex fluid systems and protects the system from contamination from the environment (col. 2, lines 32-35).

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include the reagent weight sensor of Kobashi. One of ordinary skill in the art would have been motivated to do this because, as suggested by Kobashi, because it can prevent the wasting of reagents (for example, see abstract). It would have further obvious to modify the system of Hei et al. and the reagent weight sensors of Kobashi et al. with the fluid distribution module of DeVries because DeVries shows an advantage of closed fluid distribution module is that it

simplifies the handling of complex fluid systems and protects the system from contamination from the environment.

Claims 42-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei (US PAT 6,544,727), in view of Kobashi (U.S. Patent # 5,428,993 published July 4th, 1995) and in view of DeVries (US PAT 4,379,452) as applied to claims 37-41, 44-49, 51-54, and 56-61 above, and further in view of Matkovich, US 5,126,054.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, filter with a median pore of about 0.2 microns is position between the supply module and the processing module. In some embodiments, the process chemicals are sterile. In some embodiments, a leukocyte depletion filter is position between the cell and processing modules.

Hei in view of Kobashi et al. and in view DeVries shows the system of claims 37-41, 44-49, 51-54, and 56-61, as set forth above.

Hei discloses a filter (claims 1 and 21), but Hei in view of Kobashi do not disclose a filter having a median pore diameter of about 0.2 microns and a leukocyte depletion filter.

Matkovich discloses the filtration of blood components into a receiving bag (col. 1, line13-17 and claim 1). Matkovich further discloses removing leukocytes by filtration from blood (leukocyte depletion) (col. 1, line 13- 17; col. 5-6, bridging paragraph). Matkovich discloses a filter having 0.2 micron pores (claims 5 and 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei view of Kobashi et al. and in view of DeVries applied to claims 37-41, 44-49, 51-54, and 56-61 above to use a filter to deplete leukocytes, such as taught by Matkovich, where the motivation would have been to remove harmful components, as taught by Matkovich, col. 6, line 5-9.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Kobashi (U.S. Patent # 5,428,993 published July 4th, 1995), as applied to claims 37-41, 44-49, 51-54, and 56-61 above, and further in view of Hudak, US 5,641,637.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, blood cells are A, B, AB genotype.

Hei in view of Kobashi et al. and in view of DeVries shows the system of claims 37-41, 44-49, 51-54, and 56-61, as set forth above.

Hei view of Kobashi et al. and in view of DeVries applied to claims 37-41, 44-49, 51-54, and 56-61 above do not disclose the blood cell genotypes A, B, or AB.

Hudak discloses a method for preparing cells. Specifically, Hudak discloses rare genotype cells (e.g., AB genotype) (col. 2, line 45-52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei view of Kobashi et al. and in view of

DeVries applied to claims 37-41, 44-49, 51-54, and 56-61 above to use A6 cells, such as taught by Hudak, where the motivation would have been to provide hospitals with rare cell genotype blood, as taught by Hudak, col. 2, line 45-52.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

29 April 2008

/K. R. S./
Examiner, Art Unit 1631
/John S. Brusca/
Primary Examiner, Art Unit 1631